

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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SCHERING CORP., ET AL.,

Plaintiffs,

v.

GLENMARK PHARMACEUTICALS, INC.  
USA, ET AL.,

Defendants.

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CIVIL ACTION NO. 07-1334 (JLL)

**OPINION**

**LINARES**, District Judge.

This matter comes before the Court by way of Defendant Glenmark's ("Glenmark") motion for partial summary judgment of invalidity of Claim's 10 – 13 of the '721 patent based on improper reissue under 35 U.S.C. § 251. Plaintiff Schering ("Schering") opposes the motion. This Court has considered the submissions made in support of and in opposition to the motion and decides this matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, Glenmark's motion for partial summary judgment is granted.

**I. Factual History**

For purposes of this motion, the following material facts are not disputed. On March 18, 1996 Schering filed a United States patent application as U.S. Ser. No. 08/761,751 ("the 751 application"). (Pl.'s Resp. Statement of Material Facts at ¶ 1). Claim 7 of the '751 application identified ezetimibe by its chemical name. (*Id.* at ¶ 2). Thereafter, on June 16, 1998, the United States Patent and Trademark Office ("the PTO") issued another patent with nine claims as U.S. Patent No. 5,767, 115 ("the '115 patent"). (*Id.* at ¶ 4). Ezetimibe falls within the scope of claims 1-3, 5, and 7 of the later patent. (*Id.* at ¶ 5 & 6). Ezetimibe is recited according to its chemical name in claim 7 of the '115 patent. (*Id.* at ¶ 7). Apparently, Anita Magatti, the Schering lawyer

who prosecuted the '115 patent, intended to include "bullet claims"<sup>1</sup> pertaining to ezetimibe. However, she indicates that she inadvertently (i.e., not by way of a deliberate decision) failed to include such bullet claims. (Def.'s Resp. to Pl.'s Resp. Statement ¶¶ 1 & 6).

In the year 2000, Mr. James Nelson, Schering's chief patent counsel at the time, allegedly realized for the first time that the '115 patent did not contain a bullet claim to ezetimibe. (*Id.* at ¶ 9.) Notwithstanding the absence of said bullet claim, the original 1 – 9 claims of the '115 patent were valid and enforceable. (Pl.'s Resp. Statement of Mat. Facts at ¶ 17). On June 15, 2000, Schering filed an application for reissue of the '115 patent pursuant to 35 U.S.C. § 251 to add bullet claims to ezetimibe, specifically claims 10 – 13. (*Id.* at ¶ 8). In particular, the reissue application claimed the ezetimibe compound itself, the pharmaceutical compositions of ezetimibe, and methods of treatment using ezetimibe. (Def.'s Resp. to Pl.'s Statement at ¶ 11). In support of the application, Schering submitted a declaration from Chief Patent Counsel James Nelson. Mr. Nelson declared that the reissue application did "not seek to enlarge the scope of any of the claims of the original '115 patent" (Pl.'s Resp. to Pl.'s Statement at ¶ 9). Mr. Nelson also declared that "[c]laims 10 – 13 are parallel to the original broader claims 7 – 9" and that "claims 10 – 13 are narrower in scope in that they are limited to a single compound [i.e., ezetimibe], a pharmaceutical composition containing this compound, and a method of using this compound." (*Id.* at ¶ 10).

On May 28, 2002, the PTO granted Schering's application for reissue and U.S. Patent No. RE37, 721 ("the '721 patent") issued. (*Id.* at ¶ 13). The '721 patent, as issued, retained the original claims 1 – 9 contained in the '115 patent and added the new claims 10 – 13. (*Id.* at ¶ 13). Schering did not amend or cancel any of the original claims 1-9, except to correct a typographical error in Claim 8. (*Id.* at ¶ 14).

## II. Legal Standard

A court shall grant summary judgment under Rule 59(c) of the Federal Rules of Civil Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits

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<sup>1</sup> The parties agree that a "bullet claim" "recite[s] by name all of the significant structure disclosed, omitting only the nuts and bolts. [The bullet claim] should describe the commercially most effective way to carry out the invention, including all preferred conditions. This not only protects against the copyist, but, where possible, it is desirable to assert a narrow claim against an alleged infringer, because such a claim is harder to invalidate either on newly discovered prior art or on formal grounds (too broad, etc.)." Robert C. Faber, Landis of Mechanics of Patent Claim Drafting, § 60 (4<sup>th</sup> Ed. 1999). (Glenmark's Resp. to Pl.'s Resp. Statement of Facts ¶ 2).

show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed.R.Civ.P. 56(c). The moving party first must show that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine issue of material fact compels a trial. Id. at 324. The Court must consider all facts presented and the reasonable inferences drawn from them in the light most favorable to the non-moving party. See Pa. Coal Ass’n v. Babbitt, 63 F.3d 231, 236 (3d Cir.1995).

A patent is presumed to be valid, and each of its claims are presumed valid independent of the validity of other claims. 35 U.S.C. § 282. A party asserting the invalidity of a patent or one or more of its claims has the burden of establishing such invalidity by clear and convincing evidence. Id.; Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed. Cir. 1986). “Whether the claims of a reissue patent violate 35 U.S.C. § 251 . . . is a question of law.” N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1349 (Fed. Cir. 2005).

### **III. Discussion**

Section 251 establishes the requirements for obtaining a reissue patent and reads as follows:

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

35 U.S.C. § 251. “Section 251 is ‘remedial in nature, based on the fundamental principles of equity and fairness, and should be construed liberally.’” MBO Labs., Inc. V. Becton, Dickinson & Co., 474 F.3d 1323, 1331 (Fed. Cir. 2007) (quoting In re Weiler, 790 F.2d 1576, 1579 (Fed. Cir. 1986)). However, Section 251 “‘was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute de novo his original application.’ Thus, ‘not every event or circumstance that might be labeled “error” is correctable by reissue.’” In re Serenkin, 479 F.3d 1359, 1362 (Fed. Cir. 2007) (quoting In re Weiler, 790 F.2d at 1579).

As explained in In re Wilder, 736 F.2d 1516 (Fed.Cir.1984), cert. denied, 469 U.S. 1209 (1985):

There are two distinct statutory requirements that a reissue oath or declaration must satisfy. First, it must state that the patent is defective or partly inoperative or invalid because of defects in the specification or drawing, or because the patentee has claimed more or less than he is entitled to. Second, the applicant must allege that the defective, inoperative, or invalid patent arose through error without deceptive intent.

Id. at 1518. More succinctly, “the statutorily required ‘error’ of section 251 has two parts: (1) error in the patent, and (2) error in conduct.” Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1564 (Fed. Cir. 1989). Glenmark argues that Schering’s reissue declaration is an insufficient basis for reissuance under the statute and that consequently the patent should not have been issued, and Claims 10 – 13 are invalid as a matter of law. The burden is on Glenmark to show by clear and convincing evidence that the reissue declaration is in fact insufficient under the statute given the specific circumstances of this case inadequate. The Court will analyze the second statutory requirement first.

#### **A. Error in Conduct**

In order to satisfy the second prong of the Section 251 analysis, the applicant must “allege that the defective, inoperative, or invalid patent arose through *error without deceptive intent*.” 35 U.S.C. § 251 (emphasis added). As discussed *infra* Schering alleges that the prosecuting attorney’s failure to include bullet claims regarding ezetimibe constituted error within the meaning of the statute. An error occurs “without deceptive intent” when made through inadvertence, accident, or mistake. See In re Wadlinger, 496 F.2d 1200, 1207 (noting that errors arising from inadvertence, accident, or mistake are correctable under the reissue statute).

For purposes of this motion, the parties agree that the failure of Anita Magatti - the prosecuting attorney - to include a bullet claim was an inadvertent mistake and not the result of a deliberate decision not to include a bullet claim to ezetimibe. (See Def.’s Resp. to Pl.’s Statement ¶¶ 1, 6, & 9). Therefore, in the absence of deceptive intent, Schering satisfies the second prong of Section 251.

#### **B. Error in patent.**

In order to satisfy the first prong of the Section 251 analysis the applicant - Schering - must state that the alleged error rendered the patent “wholly or partly inoperative or invalid.” 35 U.S.C. § 251. Plaintiff argues that its application satisfied the first prong of Section 251 because the failure to include bullet claims to ezetimibe in the ‘115 patent rendered the patent “wholly or partly inoperative or invalid” (Def.Br. at 14). Plaintiff also argues that its application satisfied the second prong of § 251 because the reissue statute may be “invoked to add inadvertently omitted narrow claims as a hedge against the possibility of invalidation of a broad claim” (Def. Br. at 7).

In order to satisfy the first prong of the Section 251 analysis the applicant must state that the alleged error rendered the patent “wholly or partly inoperative or invalid. Plaintiff’s argument ignores the plain language of Section 251 by effectively reading-out of the statute the following language: “wholly or partly inoperative or invalid.” 35 U.S.C. § 235. “Inoperative” has been construed as failing to adequately protect the invention. In re Handel, 312 F.2d 943, 945 n. 2 (C.C.P.A. 1963).

Construing the facts in the light most favorable to Schering it is undisputable that even in the absence of bullet claims pertaining to ezetimibe, the ‘115 patent was effective to protect ezetimibe. Plaintiff concedes that Claims 1-9 were and are valid and operative. Plaintiff concedes that Claims 1-9 in fact include ezetimibe. It follows, therefore, that Claims 1-9 of the ‘115 patent effectively protected ezetimibe and “secure[d] to [Schering] the benefits which the law intended.” Hewlett-Packard, 882 F.2d at 1564 (citing Grant v Raymond, 31 U.S. (6 Pet.) 218, 244, 8 L. Ed. 376 (1832)). The failure to include specific bullet claims to ezetimibe in the ‘115 patent did not, therefore, render the patent “wholly or partly inoperative or invalid.” 35 U.S.C. § 251. By Plaintiff’s own concession, ezetimibe was contained in a valid and operative claim. (Pl.’s Resp. St. of Mat. Facts at ¶ 17). Based on the aforementioned reasons, the Court finds that Plaintiff failed to meet the first prong of Section 251. Schering’s reissue application was improperly granted by the PTO and Claims 10 – 13 are invalid as a matter of law. Defendant’s motion for summary judgment on the ground of improper reissue is GRANTED.

The Court now turns to Plaintiff’s “hedging” argument. Plaintiff argues Section 251 may be “invoked to add inadvertently omitted narrow claims as a hedge against the possibility of invalidation of a broad claim” (Def. Br. at 7). This argument is unpersuasive. The concept of

“hedging” has only been referenced in dicta.<sup>2</sup> Kool, Mann, Coffee & Co. v. Coffey, 300 F.3d 340, 355 (3d Cir. 2002) (ruling that statement unnecessary to the court’s ruling, as dicta, are not binding); see also Cohens v. Virginia, 6 Wheat. 264, 399-400 (1821) (Marshall, C. J.) (explaining why dicta is not binding). However, even assuming *arguendo* that the concept of hedging has the force of law, said concept does not apply in the context of this case. The cases cited by Plaintiff in which hedging has been applied are factually distinguishable. Specifically, both of the cases cited by Plaintiff involve applications for reissue to protect a claim from a specific challenge.<sup>3</sup> Presumably, under such facts, the patentee would have been allowed to hedge against the specific challenge because due to an inadvertent omission the specific challenge had the potential to render the claim “wholly or partly inoperative or invalid.” Here, even when viewing the facts in the record before this Court in the light most favorable to Schering, there is nothing to suggest that due to an inadvertent omission a specific challenge had the potential to render the claim “wholly or partly inoperative or invalid.” In fact, Schering concedes that Claims 1 – 9 remain valid and enforceable. (Pl.’s Resp. Fact Statement ¶ 17). Therefore, Plaintiff could only be hedging against an unknown and unspecified potential future

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<sup>2</sup>Plaintiff cites the following cases in support of *hedging*: In re Handel, 312 F.2d 943 (C.C.P.A. 1963), Hewlett-Packard Co. v. Bausch & Lomb Inc., 882 F.2d 1556 (Fed. Cir. 1989), and Alcon Labs., Inc. v. Allergan, Inc., 1990 U.S. District LEXIS 13348 (N.D. Tex. Aug. 28, 1990). In re Handel: “Hedging” appears to have originated in In re Handel, 312 F.2d 943 (C.C.P.A. 1963) “The narrower appealed claims are simply a **hedge** against possible invalidity of the original claims should the prior use be proved, which is a proper reason for asking that a reissue be granted.” Id. at fn. 2. (emphasis added). “The sole issue in the case [was] whether the appealed claims [were] ‘for the invention disclosed in the original patent,’ as required by 35 U.S.C. § 251.” Id. at 947-48. Therefore, the issue of whether or not § 251 may be invoked to add inadvertently omitted narrow claims as a hedge against the possibility of invalidation of a broad claim were not necessary for the court’s decision and, as dicta, are not binding on this Court. Hewlett-Packard: The court did not decide “whether omission of narrow claims which more specifically cover a broadly claimed invention [i.e. the failure to hedge] meets the first prong of the requirement for error.” Hewlett-Packard Co., 882 F.2d 1556, 1665. Therefore, hedging was not necessary to the court’s decision and, as such, is dicta. The Court did, however, note that hedging had been “tacitly approved, at least in dicta, in our precedent.” Id. (emphasis added). The Court went on to say that “[f]or purposes of this case we will assume that [hedging] is in accordance with . . . the statute.” Id. Therefore, not only was “hedging” dicta, but when presented with the opportunity to give the concept the force of law it declined to do so. Alcon Labs., Inc.: Here, the Court held reissued claims invalid for failure to identify a cognizable “error in conduct” and, therefore, did not reach the “error in patent” prong. Therefore, it is the opinion of this Court, that this was an erroneous use of the Federal Circuit’s dicta as precedent ultimately had no bearing on the outcome of the case and, as such, remained dicta.

<sup>3</sup> In re Handel, 312 F.2d 943 (C.C.P.A. 1963): Patentee sought to narrow his claims to avoid invalidity in light of an alleged prior public use should to said use be proven; Nat’l Rolled Thread Die Co. v. E.W. Ferry Screw Prods., Inc., 541 F.2d 593 (6<sup>th</sup> Cir. 1976): Patentee sought reissue to avoid invalidity in light specific prior art; Alcon Labs., Inc. v. Allergan, Inc., 1990 U.S. District LEXIS 13348 (N.D. Tex. Aug. 28, 1990). The specific application of hedging in the context of this case is difficult to discern. In any event, as an unpublished opinion the court’s reasoning is not binding on this Court or the Federal Circuit. See Fed. R. App. Pr for the Fed. Cir. 32.1 (d) (“The court . . . may look to a nonprecedential disposition for guidance or persuasive reasoning, but will not give one of its own nonprecedential dispositions the effect of binding precedent.”)

challenge which does not fall within the concept of hedging as defined in dicta by the Federal Circuit. Accordingly, this Court rejects Plaintiff's argument based on hedging.

#### **IV. Conclusion**

For the aforementioned reasons, Defendant Glenmark's motion for partial summary judgment of invalidity of Claims 10 – 13 based on improper reissue is GRANTED.

An appropriate order accompanies this Opinion.

DATED: April 19, 2010

/s/ Jose L. Linares  
UNITED STATES DISTRICT JUDGE